

Duration of Use – Expiratory Valves (MP01060, MP01061)

April 2, 2020

Dear customers, dear health care professionals,

The pandemic COVID-19 has created a high demand for mechanical ventilation and the necessary accessories. Due to the high demand we experience delivery shortages for critical parts such as Expiratory Valves. According to the Instruction for Use of the Expiratory Valves we recommend a period of use up to 7 days and single-patient use due to Infection prevention and control (IPC) measurements. Because of these special circumstances, we believe it is our responsibility to provide you some information if you consider increasing the duration of use for longer than the recommended 7 days on your own responsibility. **This letter is only valid for time of delivery shortage due to the pandemic COVID-19.**

I. Legal and Regulatory Perspective

WARNING: The following information on the legal and regulatory perspective is limited to the laws in force in the European Union (EU) as of the date of this letter and provides only general guidance.

Any use of the accessories outside of the intended use and recommendations specified in the instructions for use constitutes off-label use.

If an accessory is used off-label, the user recognizes that it is not the intended use of the accessory and does so in his own responsibility and at his own (liability) risk. However, in a situation in which a patient requires mechanical ventilation but cannot be ventilated due to a lack of expiratory valves, the benefit of being able to ventilate such a patient with an expiratory valve used longer than 7 days or with multiple patients has to be weighed against the risk of the off-label use of the accessory. This risk benefit assessment and the resulting decision has to be made by the responsible health care professional based on the circumstances of the particular case.

II. Known limitations of using an Expiratory Valve for longer than 7 days/ on multiple patients

WARNING: Dräger as the manufacturer cannot and may not market or promote or sign-off such off label use of different accessories. The following information is therefore provided only to provide a better basis for the decision of the responsible health care professional. If an accessory is used off-label, the user does so in his own responsibility and at his own (liability) risk.

Our internal testing often goes further than the typical and recommended use scenarios to make sure that all devices work as specified for the recommended period of use. For safety and quality reasons the Expiratory Valve was tested for different use scenarios for longer than 7 days. Therefore the user has to weight the risks of using the Expiratory Valve up to 14 days / on multiple patients.

If it is planned to use a disposable expiratory valve longer than 7 days or with multiple patients the user is responsible to take care for the hygienic risks of such use.

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Always use a filter to prevent the contamination of the disposable expiratory valve. Adding further components such as filters may increase inspiratory and expiratory resistance of the breathing system and adversely affect the performance of the ventilator. The use of additional components requires particular care and monitoring!

- 1) Use of the Expiratory Valve longer than 7 days (one patient)**
 - use of filter e.g. SafeStar (period of use: not exceeding 24 hours) or Expiratory Heated Filter (period of use: not exceeding 7 days)
 - all filters are single-patient use only!

- 2) Use of Expiratory Valve on multiple patients**
 - use of filter e.g. SafeStar, please exchange the filter after every patient (all filters are single-patient use only!)
 - period of use: not exceeding 24 hours (SafeStar)

The user is responsible for regularly replacing the medical device according to the hospital's hygiene regulations.

The disposable Expiratory Valves cannot be reprocessed. Reprocessing or sterilization may lead to failure of the medical device and to injury to the patient.

Please follow the Instruction for Use of the main device and accessories and take all the safety related information into consideration.

If you have any questions or remarks to this topic, please do not hesitate to contact your local Dräger representative.

Kind Regards,



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